PROTOCOL

Surgical Site Infections in Major Lower Limb Amputation: A Multicentre Audit (SIMBA)

Protocol version 1.0, 01st September 2023

VERN Vascular and Endovascular Research Network

BiCOPS Birmingham Centre for Observational and Prospective Studies

1. Protocol Changes

PROTOCOL CHANGES		
Date of change	**Protocol version number**	**Summary of change**

2. Abbreviations

AKI	Acute kidney Infection
BiCOPS	Birmingham Centre for Observational and Prospective Studies
CDC	The Centres for Disease control and Prevention
DCT	Data Collection Tool
IT	Information Technology
MLLA	Major Lower Limb Amputation
PIS	Patient Information Sheet
PL	Project Lead
SMG	Study Management Group
SSI	Surgical site infection

3. Study Management Group

- Ismay Fabre, Vascular Surgery Core Trainee, South East Wales Vascular Network
- David Bosanquet, Consultant Vascular Surgeon, South East Wales Vascular Network
- Matthew Popplewell, Consultant Vascular Surgeon, Queen Elizabeth Hospital Birmingham
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- Ian Chetter, Professor of Vascular Surgery, Hull Vascular Surgical Unit
- Michael Wall, Consultant Vascular Surgeon, Russells Hall Hospital
- Tom Pinkney, Colorectal Surgery, UK
- Terry Hughes, Birmingham Centre for Observational and Prospective Studies
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4. Audit Summary

Full Audit Title	Surgical Site Infections in Major Lower Limb Amputation: A Multicentre Audit (SIMBA)
Short Title	SIMBA
Audit Design	Multicentre, prospective audit
Audit Duration	Approx. 1.5 year
Audit Objectives	**Primary Objective** 1. Compare post-MLLA SSI prevention unit performance to national and international guidelines **Secondary Objectives** 1. Describe incidence of post-MLLA SSI and wound breakdown, describe risk factors associated with these and clinical outcomes of post-MLLA SSI
Audit Outcomes	1. To compare the performance of units with NICE guidance relating to SSI prevention specifically related to MLLA 2. Capture centre specific data regarding pathways and policies surrounding MLLA and compare this to VSGBI Best Practice Clinical care pathway for MLLA (for patients under the care of a vascular surgeon). 3. Calculate a 30-day incidence of SSI post-MLLA 4. Calculate a 30-day incidence of wound breakdown post-MLLA 5. Identify the cause of wound breakdown post-MLLA (e.g. ischaemia or haematoma) 6. Calculate a 30-day incidence of revision surgery post-MLLA (to the same or higher level) 7. Identify the patient and surgical risk factors associated with MLLA SSI

	8. To calculate the incidence of complications related to SSI including, sepsis, AKI,mortality, increased LOS or admission to critical care.
Coordinating Centre	Birmingham Centre for Observational and Prospective Studies
Number of subjects	400
Eligibility Criteria	Patients are eligible for inclusion in SIMBA should they meed the following criteria: - Patients over 18 years of age - Patients undergoing MLLA - Emergency or elective MLLA (including Hip disarticulation, Above Knee, Through Knee and Below Knee) - Emergency or elective MLLA revision (defined as revision surgery which requires shortening of the bony length of the residual limb). Patients undergoing the following procedures are not suitable for SIMBA enrolment: - MLLA with complex re-constructions (e.g. myocutaneous flap) to provide coverage of the amputation site (this does not encompass patients undergoing myodesis and/or myoplasty) - MLLA with a concomitant placement of an osseous integration - Staged amputation (defined as a MLLA performed in two or more separate visits to the operating theatre)
Duration of data collection	Centres should collect data on eligible patients. Post-operative sequelae data points will be collected up until 30 days following surgery. Potenital for each patient to be be followed up at 12 months (pending approval).

5. Introduction

Surgical site infection (SSI) is a significant potential complication of any surgical procedure, acknowledged by NICE as a leading cause of in-hospital morbidity and mortality[1]. Within vascular surgery, SSI rates as high as 40% have been reported, particularly in patients undergoing lower limb revascularisation or major lower limb amputations (MLLA)[2]. The high incidence of SSI after MLLA may be contributable to the underlying risk factors affecting healing and susceptibility to SSI, including ischaemia, pre-existing infection and diabetes[3]. The Vascular Society of Great Britain and Ireland (VSGBI) provide a best practice clinical care pathway providing guidance in optimising quality of care to reduce risk of complications[4], and NICE have published guidelines regarding the prevention and treatment of SSI[5], and have recommend a variety of pre-, intra-and post-operative strategies. Moreover, wound adjuncts, such as antimicrobial dressings and negative pressure therapy, are being increasingly used with the aim to reduce SSI incidence. Compliance with these guidelines, and frequency of wound adjunct use across vascular units, is currently unknown.

To address this gap in knowledge, this multicentre audit 'SIMBA' has been created to look at MLLA SSI in detail. This audit aims to evaluate the adherence to NICE guidelines for the prevention and management of SSI, to capture centre specific data regarding the pathways and policies for management of patients undergoing MLLA, to capture incidence of SSI and wound dehiscence after MLLA, to identify the clinical sequelae for those who developed SSI and identify risk factors within this patient population. Through collection and analysis of outcome data, SIMBA will understand how well centres adhere to guidelines and identify scope for improvement regarding prevention and management of SSI after MLLA.

6. Project Aims

I. To compare the performance of units with NICE guidance relating to SSI prevention specifically related to MLLA[5]

II. Capture centre specific data regarding pathways and policies surrounding MLLA and compare this to VSGBI Best Practice Clinical care pathway for MLLA (for patients under the care of a vascular surgeon).

III. Calculate a 30-day incidence of SSI post-MLLA

IV. Calculate a 30-day incidence of wound breakdown post-MLLA

V. Identify the cause of wound breakdown post-MLLA (e.g. ischaemia or haematoma)

VI. Calculate a 30-day incidence of revision surgery post-MLLA (to the same or higher level)

VII. Identify the patient and surgical risk factors associated with post-MLLA SSI

VIII. To calculate the incidence of complications related to SSI including, sepsis, acute kidney infection (AKI),mortality, increased length of stay or admission to critical care.

6.1 Primary Objective

1. Compare post-MLLA SSI prevention unit performance to national and international guidelines

6.2 Secondary Objectives

2 Describe incidence of post-MLLA SSI and wound breakdown, describe risk factors associated with these and clinical outcomes of post-MLLA SSI

6.3 Outcomes

Outcomes are based on the short-term core outcome set for MLLA, including problems with amputation healing and infection, mortality, requirement for re-admission, re-operation or further specialist treatment for complications[7].

Outcomes will include compliance with NICE guidelines on SSI prevention. The Centres for Disease control and Prevention (CDC) define that for MLLA, SSI are wound associated infections presenting within 30 days of surgery[6]. SSI will be limited to those apparent to the treating vascular clinicians within 30 days of surgery. It is recognised that this audit may not capture milder infections treated with simple therapy in the community; this will be accounted for in analysis and dissemination.

7. Project Design

7.1 Overview

SIMBA is a multicentre audit of practice disseminated via the Vascular and Endovascular Research Network (VERN). VERN is a trainee-led national research collaborative that is run by, and engages with, research-active vascular trainees and allied health professionals, and has expertise in running national and international audits of practice.

7.2 Setting

Hospitals providing emergency and/or elective MLLA surgery in the UK and abroad, recruited via VERN. MLLA surgery can be performed within a vascular surgery department, orthopaedic department or other appropriate department. Based on current interest at least 25 units are expected to be enrolled. Whilst the best practice policies are based on UK documents, SIMBA will also capture how non-UK centres practice aligns to these guidelines.

7.3 Target population

Adults receiving emergency or elective MLLA surgery.

7.4 Eligibility criteria

The audit will capture data on consecutive patients undergoing MLLA. Any patients undergoing MLLA due to complications of PAD, DM, trauma, cancer, and other reasons are eligible for enrolment if they meet the specified criteria below. Eligible patients will be identified by screening data available to the clinical team; patients will not be approached/contacted during any part of SIMBA, and there should be no change to any patient care during the course of the audit. In patients undergoing MLLA of both limbs during the duration of SIMBA data capture, so long as the patient is eligible both sides will be included (as separate case records) in data capture.

The following criteria should be used to identify patients are eligible to be enrolled for data capture:

- Patients over 18 years of age
- Patients undergoing MLLA
- Emergency or elective MLLA (including Hip disarticulation, Above Knee, Through Knee and Below Knee)
- Emergency or elective MLLA revision (defined as revision surgery which requires shortening of the bony length of the residual limb).

Patients undergoing the following procedures are not suitable for audit enrolment:

- MLLA with complex re-constructions (e.g. myocutaneous flap) to provide coverage of the amputation site (this does not encompass patients undergoing myodesis and/or myoplasty)
- MLLA with a concomitant placement of an osseous integration
- Staged amputation (defined as a MLLA performed in two or more separate visits to the operating theatre)

7.4 Interventions

The study is observational and low risk. There are no interventions and only routinely collected data will be used.

7.5 Patient Pathway and Identification

Once a centre is open to SIMBA, data from consecutive patients undergoing MLLA meeting the eligability criteria will be collected prospectively. Data will be captured for each participant until 30 days following surgery (with a potential to extend to 1 year – see below).

Local Information Technology (IT) systems, theatre lists and in-patient lists will be used to screen for eligible patients.

In the event of a patient who previously had a MLLA outside the SIMBA audit period (not entered into SIMBA) undergoes MLLA revision, this patient is suitable for data capture and should be recorded as such in REDCap.

In the event of a patient already enrolled into SIMBA returning to theatre for revision of amputation (during the data capture period of SIMBA), this would be recorded as a "return to theatre" on the original data record and data entry for this record must be completed.

In the event of a patient already enrolled into SIMBA for an amputation on one limb has an amputation of the other (contralateral) limb, data regarding the second amputation should be entered into SIMBA as a new record.

8. Data Collection

8.1 Patient Entry

Key demographic data, baseline variables and intra-operative data should be collected as early as possible following MLLA surgery, ideally at the completion of the operation.

Once eligibility is confirmed, the baseline DCT should be completed. When the data are uploaded onto the SIMBA REDCap database, a unique REDCap identifier will be allocated to the patient. This unique study number will be used in all correspondence between the SIMBA study office and the site. Linkage between the REDCap ID and patient should be maintained securely at hospital site.

Post-operative sequelae data points will be collected up until 30 days following surgery. In the case of SSI development, further details will be required regarding extent of infection and subsequent patient outcomes. Data obtained using patient notes and electronic records; pre-operative assessment, clinic letters, theatre IT systems, discharge summary and A&E and GP records (where available). No changes

to normal follow up will be made and the patient will not be contacted to enquire about SSI unless this is standard in centre-specific care. SSI will be defined as per the 2023 CDC criteria[6].

8.2 Clinical outcomes

Data collected by clinical team at index admission, 30-day and 1 year follow up:

1. Basic patient demographics
2. Indication(s) for MLLA
3. Intra-operative data including type of MLLA performed
4. 30 day mortality incidence
5. 30-day SSI/wound breakdown incidence, and (if applicable) sequaelae of this
6. 30-day complication rate
7. (If applicable – see below) 1-year mortality, MLLA revision and ambulation rates

8.3 Site level data

On enrolment to SIMBA, each centre will be asked to complete a baseline unit survey. This will collect data on individual centres clinical care pathways and policies surrounding MLLA.

8.4 Recruitment Projection

Based on this estimation, with 25 centres taking part in SIMBA, it is anticipated that data on up to 400 patients may be captured over a 6 month period. We will however, be happy to exceed this number in terms of both number of centres and number of patients.

Estimated milestones are:

First patient recruited: 1st October 2023

Last patient recruited: 1st April 2024

Last follow up data point (30-day outcomes): 1st May 2024

Last follow up data point collected (30-day outcomes): 1st June 2024

Last follow up data point (1-year outcomes): 1st April 2025

Last follow up data point collected (1-year outcomes): 1st May 2025

9. Statistical Considerations

The statistical analysis of this audit will be undertaken by our statisticians based within the Institute of Applied Health Research at the University of Birmingham. The report of the audit will be prepared in accordance with the guidelines as set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational studies.

Continuous variables will be summarised with means and standard deviations; frequencies and percentages will be used for categorical variables. Univariate and multivariate analyses will be assessed by appropriate statistical techniques. Multilevel-logistic regression models will be used to allow for clustering at a centre or a country level**.** A p-value of <0.05 will be considered significant for all statistical methods used and the analysis will be completed using appropriate statistical software. The performance of individual hospitals will not be disclosed and all subgroup analysis will include large patient cohorts to protect patient anonymity. No surgeon- or hospital-specific comparisons will be performed in the final dataset.

10. Data Handling and Record Keeping

10.1 Data Management

Data will be collected at the following times:

- At the time or MLLA
- At 30 days post operatively.
- Funding will be sought to keep the REDCap database open and permit the follow up of patients one year after their MLLA. This will be to assess the impact of SSIs on longer-term outcomes after MLLA. Data on mortality, ambulation status, and need for revision surgery, will be collected. If this is feasible, one more team member can be added to the existing team to support the return of one-year data. It is expected that the overseeing consultant/attending will not change.

Data will be entered directly onto the SIMBA REDCap database by study collaborators at participating hospitals sites. REDCap[9, 10] is a secure, web-based software platform designed to support data capture of single and multi-site studies.

Source data will be used and uploaded electronically using an internationally recognised secure web application for building and managing online databases (REDCap). It is encouraged that data will be uploaded directly to REDCap as close to the time of surgery as possible. Paper data collection tool (DCTs) will be provided to centres to facilitate data capture when direct upload to REDCap is not possible at the time of surgery. No patient identifiable data will be transferred to REDCap.

Site study collaborators will be provided with a paper copy of the eDCT to facilitate data collection. If this is used, they should then transfer data from the paper DCT to the online SIMBA database located at https://www.bistc.redcap.bham.ac.uk. SIMBA data management staff will check all incoming data

DCTs for completeness, data consistency and compliance with the protocol. If discrepancies or missing data are identified, the SIMBA data management staff will raise queries with the research team at the participating hospital.

Data validation comprises confirmation of case ascertainment and data accuracy. At the close of the data capture timeframe, centres will be asked to review theatre logs to ensure that all patients undergoing MLLA during the data-collection timeframe were entered. Any patients not included will be added retrospectively; it is appreciated that not all data may be available retrospectively, but the SIMBA team will account for this during analysis and dissemination.

10.2 Missing Data

The online database has been designed to allow sites to securely access an individual patient's data for all DCTs throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with > 5% missing data in mandatory fields (i.e. < 95% data completeness) will be excluded from the study, as is standard within international collaborative audits[8].

10.3 Data Security and Data Protection

The security of the study database system is governed by the policies of the University of Birmingham. The SIMBA database will be hosted on the University's REDCap system managed and maintained by BiCOPS.

Data management and data security within the BiCOPS will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. The study will be conducted at collaborating sites in accordance with the current data protection requirements. Data will be acquired and stored on the REDCap platform. Access to data will be restricted, each individual collaborator entering data for SIMBA will have their own username and password. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable.

10.4 Confidentiality

Patient identifiable information will not be collected in this study. All participant data held at the University of Birmingham will be anonymised.

All data collected about participants will be identified using only a unique SIMBA study number (REDCap ID). This number will be automatically allocated via REDCap once a new patient record is created in the SIMBA database.

Any correspondence between the SIMBA study office and hospital sites will use the SIMBA study number only.

The linkage between REDCap study ID and participants will be maintained in strict confidence at participating sites. This data will not be submitted to the SIMBA study office and will not be sent outside of the participating site. A template document will be sent to centres on enrolment to be overseen by the local lead, who will be responsible for ensuring this file is only stored on-site, is done so securely

Confidentiality of all participants' data will be maintained and there will be no disclosure of information by which participants may be identified to any third party other than those directly involved in the treatment of the participant. The participants will not by identifiable with regards to any future publications relating to this study.

11. Ethical Approval

Every participating centre will register the audit locally prior to data collection (audit and service provision registration at all NHS sites involved). This audit does not require approval from the NHS Research Committee as per guidance by the healthcare Research Authority (see appendix 1) Centres outside of the United Kingdom should comply with local regulations.

The audit is required to be registered with each participating centre prospectively, prior to data collection. This is typically with the audit department, or 'Research and Development' department. Participating centres outside of the UK must comply with local regulations prior to commencement. The audit is open to all centres that undertake elective and/or emergency MLLA. In the case of UK vascular units, often they comprise of a Hub and Spoke type model. A registered Hub site may be able to undertake data collection for the Spoke sites without registering the spoke site separately.

11.1 Audit Administration

The audit has been developed by an study management team with expertise in MLLA surgery. The project will be under the auspices of the Project Lead (PL) and the Birmingham Centre for

Observational and Prospective Studies. The project will be overseen by a Study Management Group (SMG). This SMG will be chaired by the PL.

12.1 Local Study Teams

Each centre will require the support of a named supervising consultant/attending (or equivalent), who will act as guarantor of all activity undertaken at that centre, and a data collection team.
Each participating centre will be responsible for identifying a Site Leads and a data collection team. The site lead should be at least of a consultant level or equivalent. Where feasible the use of trainee collaboratives will be encouraged to aid in the delivery of this study. The role of Site Lead is to:

- Promote the audit at site and facilitate delivery at site
- Liaise with the SMG
- Ensure that mechanisms for upload of data relating to eligible participants is in place
- Ensure appropriate local staff resources are maintained (cover provided for absence) to deliver the audit

The local audit team will be responsible for data collection and data validation. This team will comprise a maximum of a supervising consultant/attending and a further 6 individuals, and can include medical trainees or allied healthcare professionals.

12.2 Publication Policy

The PL will co-ordinate dissemination of data from this audit. All publications using data from this audit to undertake original analyses will be submitted to the SMG for review before release. The success of the study depends on a large number of clinicians. For this reason, credit for the results will not be given to the committees or central organisers, but to all who have collaborated and participated in the study. Acknowledgement will include all local co-ordinators and collaborators, members of the study committees, the SMG and administrative staff. Authorship at the head of the primary results paper will be cited as a collaborative group to avoid giving undue prominence to any individual. All contributors to the study will be listed at the end of the report, with their contribution to the project identified. Those responsible for other publications reporting specific aspects of the audit may wish to utilise a different authorship model, such as “[name], [name] and [name] on behalf of the collaborative Group”. Decisions about authorship of additional papers will be discussed and agreed by the Project lead and the SMG.

To qualify for PubMed-citable collaborative co-authorship individuals must have either;

- Had a significant role in the set up and management of the study, including audit department registration, creation of a data collection team and engagement with VERN to ensure timely upload of data (with validation) and completion of the questionnaire

OR

- Captured sufficient data to warrant authorship – this would be the equivalent of collecting baseline and follow up data on approximately 10 patients, although it is appreciated individuals may participate in only baseline data collection or only follow up data capture. Data collection is expected to be complete (>95% variables completed), and submitted in a timely manner

OR

- (For consultants/attendings) provided oversight and support as detailed in the ‘‘Centre Eligibility and Team Roles” section.

The local lead at each centre will be responsible for ensuring that the SIMBA Management Group have the names and contact details of all collaborators who qualify for collaborative co-authorship at their centre. All collaborators will be given the opportunity to review draft paper(s) prior to submission. Whilst the SIMBA team appreciates the importance of this step, the team are also keen to ensure this stage does not add to significant delays in submission. All collaborators should inform the team of any changes in email addresses, and ensure their emails are checked regularly, as this stage will deliberately be kept short. Unless there are major issues or questions identified, collaborators will be given a single opportunity to comment on the paper before it’s returned to the writing group for further review within 72 hours. The writing group will make a final decision regarding the comments and edits made during this process.

Plain language summaries will be created and distributed to national amputation charities and key stakeholders.

12.3 Dissemination of Research Findings

The results of this audit will be submitted for publication in peer reviewed scientific journal, given the international nature of this audit it is anticipated that this will be reflected in the journal selected. Results of the audit will also be presented at meetings both national and international, according to the contributing nations. The findings of this audit may be used to inform the design of further studies into MLLA SSI prevention.

12.4 Finance and Funding

This audit has been funded by the National Institue of Health and Care Research Health Technology Assessment (HTA) Application Acceleration Award (22/104). The project will be coordinated via Birmingham Centre of Observational and Prospective Studies and thus the burden of the cost will lie within the UK. Participating centres will not bear any costs for being part of this audit. Similarly, no financial reimbursement will be made to units or investigators for their involvement.

12. References

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9. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.
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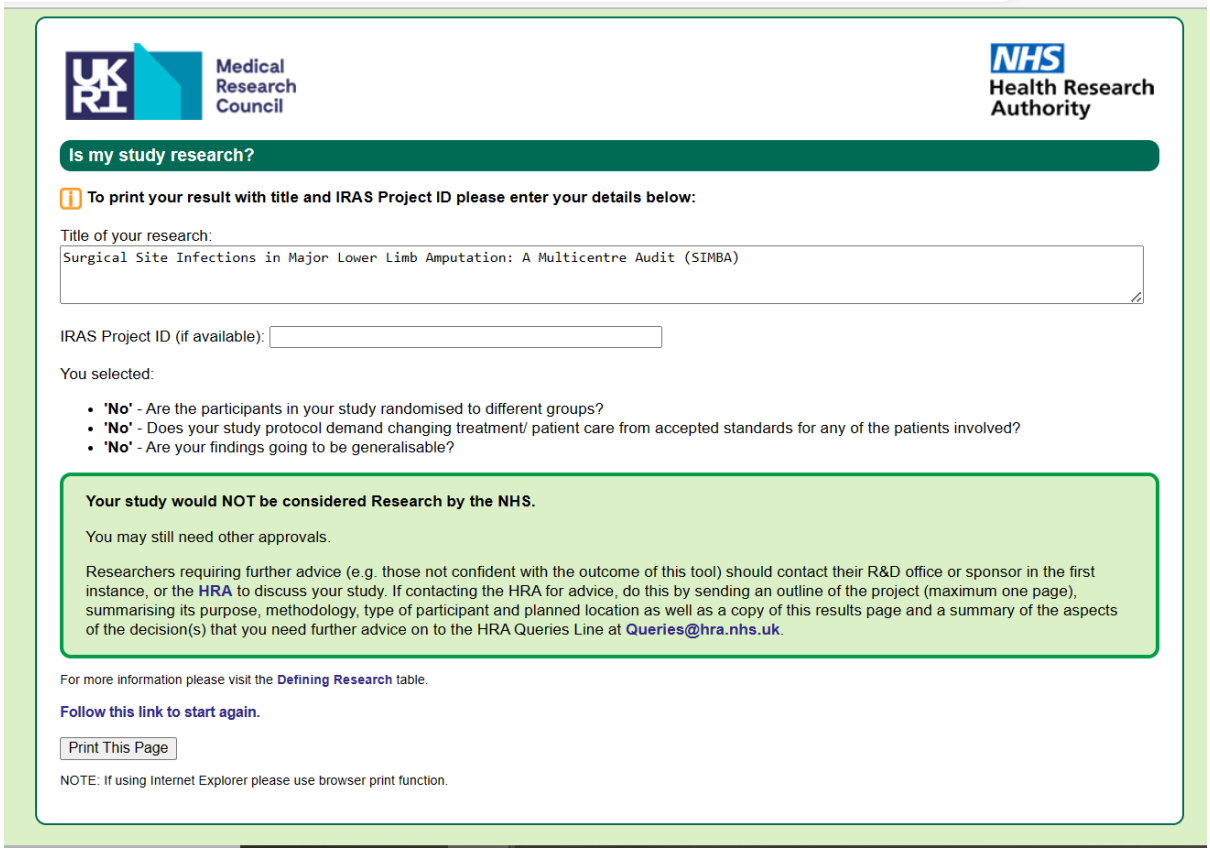
14. APPENDIX

HRA decision tool



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Title of your research:

Surgical Site Infections in Major Lower Limb Amputation: A Multicentre Audit (SIMBA)

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You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

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